Senate Finance Committee

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BAUCUS, GRASSLEY ASK FDA TO ACCOUNT FOR FINDINGS OF NEW REPORT

WASHINGTON — Sens. Max Baucus and Chuck Grassley have asked the Commissioner of the Food and Drug Administration to respond to a new independent review of the computing system used by the drug safety agency to conduct post-marketing surveillance of drugs and devices.

The November 2006 report of the Breckenridge Institute hasn't previously been made public. A copy of most of the report is attached to this email. The text of the letter to Commissioner von Eschenbach is below.

"I'm all for agencies investing in advanced technology, but if they're going to spend millions of dollars and stake Americans' health on that technology, then it really ought to work," said Baucus. "We all rely on the FDA for drug safety, and this report raises some troubling questions about how wisely the FDA spends money and how well they're protecting us."

"This report is more evidence of a broken-down process inside the FDA," Grassley said. "It echoes findings by the Institute of Medicine, the Government Accountability Office, watchdog groups, and Finance Committee investigations. It's got to be a top priority for the FDA to make new life-saving and life-enhancing drugs available to the public, and it's also got to be a top priority for the FDA to reveal new safety concerns after drugs are on the market and more information is available."

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March 1, 2007

Andrew C. von Eschenbach, M.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. von Eschenbach:

Thank you for responding to our letter of January 24, 2007 requesting documents in connection with services supplied to the Food and Drug Administration (FDA) by the Breckenridge Institute (BI). BI was hired to conduct an independent verification and validation of the Adverse Events Reporting System (AERS) II Requirements Process, the computing system that FDA uses to, among other things, carry out its post-marketing drug safety function (PMDS).

It is well established that FDA is responsible for the pre-market and post-marketing safety and efficacy assessment of drugs and some biologics. The FDA fulfills this responsibility through two main Centers: the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). One critical element in FDA fulfilling its responsibilities, particularly for PMDS, is keeping apprised of adverse events associated with the use of a drug and/or biologic. In other words, to ensure that FDA properly conducts PMDS throughout the entire life cycle of a particular product, it relies heavily upon adverse event data.

Originally, FDA operated and maintained an adverse event data system called the Spontaneous Reporting System (SRS). Over time, and as the frequency of adverse event reporting increased, SRS was deemed to be technologically inadequate. In response, FDA initiated efforts to develop a newer and better system to replace SRS that would address many of the inadequacies of that earlier system. Consequently, AERS-I became the primary post-marketing reporting system. According to the BI report, AERS I was "…designed to utilize state-of-the-art technology to facilitate the collection, analysis, and dissemination of post-marketing spontaneous reporting information." (p.9) In sum, AERS-I was intended to better equip FDA employees to protect the public safety and was part of a larger project to "revitalize the human drug post-marketing surveillance program…." (p.10)

Unfortunately, BI had a number of startling and negative findings in its report and tracks, in great detail, FDA's actions to replace an earlier version AERS system that was deemed to be "dysfunctional."

In its Executive Summary, BI states that based upon the information and data evaluated, the assessment team identified one root-cause finding and several recommendations for correction. In pertinent part, BI states, under the heading "Root Cause Finding" that

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"CDER's culture can be characterized as one in which managers at all organizational levels fail to move from the awareness of organizational problems, to the kind of action that will produce positive change. When some CDER managers do attempt to make positive change as with the AERS-II system …their attempts are frustrated and undermined by an "invisible bureaucracy" that they don't really understand. In the case covered in this report, the AERS-II system could have been completed in 2005, but was delayed and ultimately shelved, by: a) a change in project scope from replacing the dysfunctional AERS system to building an FDA-wide adverse event reporting system, and b) unilateral decisions and questionable procurement practices….These actions were taken despite the documented needs of AERS users, and the documented objections of CDER managers and scientists."

BI then goes on to describe the consequence of these actions to include the:

1) unnecessary expenditure of $1.5M for conducting an AERS-II requirements process;
2) the selection and utilization of contractors that had a "known and documented track record of inadequate or poor performance;"
3) a total estimated "cost of $25,000,000 and a four-to-five year delay in replacing the AERS system, which will not be operational until 2009 or 2010;" and lastly but perhaps most importantly the
4) "frustrating and undermining of the post-marketing drug safety work of Safety Evaluators, epidemiologists, and personnel in the Offices of Compliance and FOI because they lack some of the basic tools they need to perform their jobs, e.g. a computing system that meets their requirements."

Perhaps one of the most telling statements made by BI is that it is convinced that the "root cause of the problems associated with the AERS-II requirements processes is cultural and can only be addressed by a significant change in CDER's culture."

Unfortunately, Dr. von Eschenbach, this report does not stand alone. It must be read in light of other reports, evaluations and investigations conducted at the FDA. Indeed, when coupling the BI report with the work of the Government Accountability Office, the Institute of Medicine and of Finance Committee, we are faced once again with a devastating picture of the FDA that goes to the heart of its ability to successfully fulfill its mission for the American people.

Additionally, the BI report raises a number of other issues including: 1) how effective CDER is at managing its portfolio of information technology projects; 2) the criteria by which contractors are screened and selected to conduct projects at the FDA; and 3) the way that financial resources are being combined into larger categories in CDER's Office of Management and Budget's Exhibit 300. As a result of these concerns, we asked the Office of the Inspector General at the Department of Health and Human Services to examine these issues and report back to us in the near term. A copy of that request is attached for your review.

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In closing, we would greatly appreciate receiving a briefing from the FDA regarding the BI report no later than April 2, 2007. In addition, we would appreciate receiving a copy of Appendix D that was missing from the version of the BI report that you provided to us.

Thank you in advance for your assistance.

Sincerely,

Max Baucus
Chairman
Committee on Finance

Chuck Grassley
Ranking Member
Committee on Finance

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